NO:50; BoPAG 19 has the sequence of SEQ ID NO:52; BoPAG 20 has the sequence of SEQ ID NO:54 and BoPAG 21 has the sequence of SEQ ID NO:56 with a monoclonal antibody preparation.

REMARKS

I. Status of the Claims

Claims 1-14 and 30-34 and 182-183 are pending in the application and stand rejected under 35 U.S.C. §102(b) and 35 U.S.C. §103. Claims 12-14 and 182-183 have been amended herein to correct clerical errors. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Telephonic Interview Summary

On March 11, 2002 Applicants' undersigned representative and Examiner Cook held a teleconference to discuss claim 1 in the case. The shortcomings of the Roberts *et al.* and Zoli *et al.* references, which are set forth below, were discussed. It was indicated by the Examiner that although Roberts *et al.* and Zoli *et al.* refer to PAGs that are present more than two months post-partum, the rejection would be maintained because claim 1 refers to PAGs absent "about" two months post-partum. No agreement was thus reached.

III. Formalities

1.) The Action has objected to the drawings. In response, Applicants again note that formal drawings will be filed upon the allowance of the instant case.

2.) The Action objects to the list of references in the specification as not being a proper information disclosure statement (IDS). In response, Applicants note that an IDS has

been filed in the case in compliance with 37 C.F.R. §1.97 and 37 C.F.R. §1.98. Applicants have not alleged that the list in the specification is an IDS. Removal of the objection is thus requested.

3.) The Action objected to the IDS filed 10/1/99 as failing to comply with 37 C.F.R. §1.98(a)(3) because the IDS does not include a concise explanation of the relevance of reference B1 (PCT WO 99/06038), which is not in English. In response, Applicants note that the reference includes an English abstract and, accordingly, no translation is required. Removal of the objection is thus respectfully requested.

4.) The Action objects to claims 12-14 as depending from canceled claim 9. In response, Applicants note that the claims have been amended to depend from claim 1. The objection is now moot in light of the amendments and removal thereof is thus respectfully requested.

IV. Rejections Under 35 U.S.C. §102(b)

A. Roberts et al. (1995)

Claims 1, 3, 5, 6, 9 and 14 remain rejected under 35 U.S.C. §102 as anticipated by Roberts *et al.* (1995). The examiner characterizes the reference as teaching evaluation of maternal serum concentrations for PAGs, and correlating measurement to pregnancy in cattle and sheep. Applicants respectfully traverse.

The cited reference does not teach PAGs meeting the claim limitations. Claim 1, upon which each of the remaining claims depends, reads as follows:

1. A method for detecting pregnancy in a bovine animal comprising:

(a) obtaining a sample from said animal; and

(b) contacting said sample with an antibody that binds immunologically to at least one pregnancy associated antigen (PAG), wherein said PAG is present in early pregnancy and absent at about two months post-partum; and

(c) detecting said PAG bound to said antibody;

whereby the presence of said PAG in said sample indicates that said animal is pregnant.

Roberts *et al.*, however, does not disclose a PAG that is "present in early pregnancy and absent at about two months post-partum". For example, in the last two sentences of the first full paragraph on page 233 of Roberts *et al.*, it is indicated that PAG-1 has an apparent long half-life and that "[b]ecause concentrations at term may be well above 1 μg/ml, *it requires at least 3 months for levels to drop back to threshold values* (Fig. 1), and cows are customarily bred within 2 to 3 months after calving." Emphasis added. A review of the referenced figure 1, which is also given in Zoli *et al.*, 1992, demonstrates this, showing that mean bPAG levels were above 1 ng/ml at 80 days post-partum. A review of the Zoli *et al.* abstract, indicates that the undetectable level for serum bPAG levels was less than 0.20 ng/ml. It is thus apparent that Roberts *et al.* does not teach PAGs meeting the claim limitations.

As indicated above, Applicants understand that it is the position of the Examiner that the rejection was maintained because, based on the use of the term "about" two months, the PAG taught by Roberts *et al.* could potentially be viewed as absent *about* two months post-partum. However, the PAG described by Roberts *et al.* is indicated to be present at least three months post-partum. This cannot be said to be about two months, as this is a figure 50% greater than two months. The term "about" is well known to those of skill in the art and does not allow for such a discrepancy. For example, the Encarta™ online dictionary (http://dictionary.msn.com), gives the meaning of the relevant usage of the word as a preposition as "approximately: close to in number, time, or degree". Appendix C. The relevant definition of "about" from the online

version of the Merriam Webster's Collegiate Dictionary™ (http://www.m-w.com) is "reasonably close to". Appendix D. Therefore, an interpretation of "about two months" to include three months simply does not fit the meaning of the term as it is understood by those of skill in the art. Without teaching such a PAG, the cited reference cannot anticipate the claims.

In view of the foregoing, removal of the rejection is respectfully requested.

B. Zoli et al. (1992)

Claims 1, 3, 5, 6, 9 and 13 remain rejected under 35 U.S.C. §102 as anticipated by Zoli *et al.* (1992). The reference is cited as disclosing a double-antibody RIA for BoPAGs, and measuring BoPAG levels during pregnancy in cows. Applicants respectfully traverse.

Applicants again note that the cited reference fails to teach PAGs meeting the claim limitations. For example, attention is drawn to the Abstract of Zoli, which indicates that peripheral serum bPAG concentrations were 1.44 +/- 1.08 ng/ml at day 90 post partum. Thus the mean bPAG concentration of at least 0.36 ng/ml at 90 days post-partum was nearly twice the indicated undetectable level of <0.20 ng/ml that was given in Zoli *et al.* At most, the level was 2.52 ng/ml, or more than 10 times the undetectable level. As indicated in the Action, the undetectable concentration was not reached until day 100 +/- 20 pp.

The problem created by the late presence of the Zoli *et al.* PAG is acknowledged on page 89 of Zoli *et al.*, where it is stated that "[o]verall, the presence of bPAG in sera for nearly 100 days pp constitutes a problem for subsequent diagnosis of pregnancy by this method if rebreeding occurs less than 80 days pp." Thus, again, the mean bPAG levels detected by Zoli *et al.* did not drop below undetectable levels until more than 3 months post-partum. Even if one were to assume that the Zoli *et al.* bPAG was present at least 80 days post-partum, this figure

cannot be considered to be "about two months" As described above, the term "about" as it is used herein is known to those of skill in the art to indicate a number that is close or reasonably close to a referenced figure. However, 80 days is approximately 33% longer than two months. This is cannot reasonably be construed to be "close" in time to two months. As such, the absence of this element from the prior art means that an anticipation rejection will not stand. Reconsideration and withdrawal of the rejection is thus, again, respectfully requested.

V. Rejections Under 35 U.S.C. §103

A. Claims 4, 7 and 8

Claims 4, 7 and 8 are rejected as obvious over Roberts *et al.* (1995) or Zoli *et al.* (1992) in view of Sasser *et al.* (1989). In particular, Roberts *et al.* and Zoli *et al.* are cited as above and Sasser *et al.* is cited as teaching use of saliva, milk or urine as samples to PAG. Applicants traverse the rejection.

As indicated above, regardless of what Sasser *et al.* may or may not disclose regarding means of sampling PAGs, it clearly does not address the material element of "at least one pregnancy associated antigen (PAG), wherein said PAG is present in early pregnancy and absent at about two months post-partum." Moreover, Sasser *et al.*, just like Roberts *et al.* and Zoli *et al.*, provides no indication that such PAGs even exist. Therefore, the Action has not shown that the prior art teaches or suggests all of the limitations of the claims, as is required under 35 U.S.C. § 103. *See, e.g., In re Vaeck* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Absent such a teaching, one of skill in the art would lack a reasonable expectation of success in arriving at the claimed invention. Therefore, the claims cannot be considered obvious.

In view of the foregoing, applicants respectfully request reconsideration and withdrawal of the rejection.

B. Claims 30-34

Claims 30-34 remain rejected over Roberts *et al.* (1995), Zoli *et al.* (1992) in view of Xie *et al.* (1997) and Gerrie *et al.* (1986). Roberts, *et al.* Zoli *et al.* and Xie *et al.* are cited as above and Gerrie *et al.* is cited as teaching an ELISA for PAG. Applicants traverse the rejection.

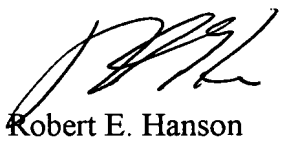
First, applicants point out that the human pregnancy-associated α2-glycoprotein is completely unrelated to the PAGs being discussed here, which are found only in Artiodactyls. Thus, to the extent that the examiner is attempting to extrapolate more from Gerrie *et al.* than an ELISA based-assay for diagnosing pregnancy, applicants submit that such is not merited. In fact, it should be pointed out that a variety of different assay formats may be employed according to the present invention, including but not limited to ELISA, RIA, Western blot, dot-blot and lateral flow technology.

More to the point, and irrespective of what Gerrie may or may not disclose regarding human PAGs, it clearly does not address the material element of "at least one pregnancy associated antigen (PAG), wherein said PAG is present in early pregnancy and absent at about two months post-partum." That is, Gerrie *et al.*, just like Roberts *et al.*, Zoli *et al.* and Xie *et al.*, provides no indication that such PAGs even exist. It, therefore, remains pure hindsight to argue that any of these references can suggest, with sufficient motivation or the requisite likelihood success, the currently claimed invention. Thus, in light of the foregoing, applicants respectfully request reconsideration and withdrawal of the rejection.

VI. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. Should Examiner Cook have any questions regarding this response, a telephone call to the undersigned in invited.

Respectfully submitted,



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MARKED-UP COPY OF CLAIMS

12. (Amended) The method of claim [9] 1, wherein said detection comprises ELISA.

13. (Amended) The method of claim [9] 1, wherein said detection comprises RIA.

14. (Amended) The method of claim [9] 1, wherein said detection comprises Western blot.

182. (Amended) The method of claim 10, wherein BoPAG 2 has the sequence of SEQ ID NO:25, BoPAG4 has the sequence of SEQ ID NO:27, BoPAG5 has the sequence of SEQ ID NO:28, BoPAG6 has the sequence of SEQ ID NO:29, BoPAG7 has the sequence of SEQ ID NO:30, BoPAG9 has the sequence of SEQ ID NO:32, BoPAG 7v has the sequence of SEQ ID NO:40; BoPAG9v has the sequence of SEQ ID NO:42; BoPAG 15 has the sequence of SEQ ID NO:44; BoPAG 16 has the sequence of SEQ ID NO:46; BoPAG 17 has the sequence of SEQ ID NO:48; BoPAG 18 has the sequence of SEQ ID NO:50; BoPAG 19 has the sequence of SEQ ID NO:52; BoPAG 20 has the sequence of SEQ ID NO:54 [or] and BoPAG 21 has the sequence of SEQ ID NO:56 with polyclonal antisera.

183. (Amended) The method of claim 11, wherein BoPAG2 has the sequence of SEQ ID NO:25, BoPAG4 has the sequence of SEQ ID NO:27, BoPAG5 has the sequence of SEQ ID NO:28, BoPAG6 has the sequence of SEQ ID NO:29, BoPAG7 has the sequence of SEQ ID NO:30, BoPAG9 has the sequence of SEQ ID NO:32, BoPAG 7v has the sequence of SEQ ID NO:40; BoPAG9v has the sequence of SEQ ID NO:42; BoPAG 15 has the sequence of SEQ ID NO:44; BoPAG 16 has the sequence of SEQ ID NO:46; BoPAG 17 has the sequence of SEQ ID NO:48; BoPAG 18 has the sequence of SEQ ID NO:50; BoPAG 19 has the sequence of SEQ ID NO:52; BoPAG 20 has the sequence of SEQ ID NO:54 [or] and BoPAG 21 has the sequence of SEQ ID NO:56 with a monoclonal antibody preparation.